

**REMARKS/ARGUMENTS**

Claims 1-12 and 27-35 are pending in this Application.

Claims 1, 3, 4, 8, 10, 11, 27, 29, 30, and 34 are currently amended. Applicants submit that support for the claim amendments and the newly added claims can be found throughout the specification and the drawings.

Claims 1-12 and 27-35 remain pending in the Application after entry of this Amendment. No new matter has been entered.

In the Office Action, claims 1, 2, 4, 5, 8-12, 27, 28, 30, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over “Stability Lab Information Manager” (hereinafter “SLIM”). Claims 3 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over SLIM in view of U.S. Patent No. 6,167,523 to Strong (hereinafter “Strong”). Claims 6, 7, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over SLIM in view of U.S. Patent Application No. 2002/0133395 to Hughes et al. (hereinafter “Hughes”).

**Claim Rejections Under 35 U.S. C. § 103(a)**

Applicants respectfully traverse the rejections to claims 1-12 and 27-35 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based on SLIM, and those in view of Strong and/or Hughes. The Office Action alleges that claimed invention is directed to obvious subject matter, in that the combination of SLIM, Strong, and Hughes expressly or impliedly suggest the claimed invention or that a convincing line of reasoning has been presented as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the SLIM, Strong, and Hughes.

Applicants, however, respectfully submit that a prima facie case of obviousness has not been established by the evidence presented in the Office Action. To reach a proper determination under 35 U.S.C. § 103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the Examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of the disclosure must be put aside in reaching this

determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon the disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (M.P.E.P. § 2142).

Applicants respectfully submit that SLIM, Strong, and Hughes, either individually or in combination, fail to disclose one or more of the claim limitations recited in each of claims 1-12 and 27-35. These differences, along with other difference, establish that the subject matter as a whole of claims 1-12 and 27-35 would not have been obvious at the time of invention to a person of ordinary skill in the art.

For example, amended claim 1 recites displaying one or more interfaces that allow a user to create stability studies. As recited in amended claim 1, one or more first interfaces are displayed and input is received via these one or more first interfaces indicative of a set of requirements for a first stability study. The Office Action alleges that SLIM discloses the above-recited feature. However, Applicants respectfully disagree.

On page 3, the Office Action alleges that SLIM discloses the one or more first interfaces recited in amended claim 1 by interpreting SLIM to disclose the interfaces by the Lab Work Request data entry forms of SLIM on page 4, line. However, SLIM disclose that the LWR data entry forms “are interactive forms that allow the user to enter results on screen.” (Emphasis added). Applicants respectfully submit that interactive forms that accept results of a stability study as in SLIM are substantially different from the one or more first interfaces as recited in amended claim 1 that enables a user to create stability studies by specifying requirements that need to be fulfilled for the stability studies. Thus, Applicants respectfully submit that SLIM fails to disclose the feature recited in amended claim 1 of “displaying one or more first interfaces that enable a user to create stability studies by specifying requirements that need to be fulfilled for the stability studies” and “receiving input via the one or more first interfaces indicative of a set of requirements for a first stability study.”

Moreover, amended claim 1 recites displaying one or more second interfaces that enable a user to create workflows associated with stages of stability studies, a workflow

including information configured to prompt a user to perform one or more actions that need to be taken during a stage associated with a stability study in order to fulfill requirements specified for the stability study. The Office Action again alleges on page 3 that the LWR forms allow the user to specify actions. However, SLIM merely specifies that the user enters results through the LWR forms. Accordingly, Applicants respectfully submit that SLIM fails to disclose the features recited in amended claim 1 of “displaying one or more second interfaces that enable a user to create workflows associated with stages of stability studies, a workflow including information configured to prompt a user to perform one or more actions that need to be taken during a stage associated with a stability study in order to fulfill requirements specified for the stability study” and “receiving input via the one or more second interfaces indicative of a set of workflows associated with a plurality of stages of the first stability study, each workflow specifying a set of actions to be performed that need to be taken during for each stage in the plurality of stages of the first stability study.”

Furthermore, amended claim 1 recites displaying one or more third interfaces that enable a user to specify a set of business rules for stability studies. The Office Action again alleges on page 3 that the LWR forms allow the user to specify a set of business rules. Applicants respectfully submit that the results entered on screen in the LWR forms of SLIM are substantially different from a set of business rules as recited in amended claim 1. Accordingly, Applicants respectfully submit that SLIM fails to disclose the features recited in amended claim 1 of “displaying one or more third interfaces that enable a user to specify a set of business rules for stability studies” and “receiving input via the one or more third interfaces indicative of a set of business rules for the first stability study.”

In another example, amended claim 1 recites validating the received input information against the set of business rules for the stability study to determine whether the input information is acceptable. The Office Action alleges that SLIM discloses the above-recited feature in that SLIM allegedly provides for the verification of data entered in the LWR forms. However, the fact that data passes through a verification state and an approval state does not expressly nor inherently disclose that the data in SLIM is validated against a set of business rules as recited in amended claim 1. SLIM does not expressly disclose that the verification process

includes validating the results entered in the LWR forms of SLIM against a set of business rules as recited in amended claim 1. Furthermore, to establish inherency, “the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Office Action is merely alleging the possibility that business rules are used in the verification process of SLIM. More likely than not, the results in SLIM are merely being verified for accuracy, such as formatting, double checking the input, whether the source is correct, or the like. The Office Action cannot reasonably interpret the bare fact the results are verified in SLIM to include that results are validated against business rules as recited in amended claim 1.

Finally, the Office Action acknowledges that SLIM fails to provide at least the first through third interfaces as recited in amended claim 1. The Office Action alleges that it would have been obvious to simply repeat “the process” for a first, second, or third time. Applicants note that “the process” identified by the Office Action is the process of entering results in the LWR forms on screen in SLIM. Applicants respectfully submit that no matter how many times the LWR forms for displayed, and the results of the study are entered, the user of SLIM still does not see a first interface that enables the user to create the study, or a second interface that enables the user to create workflows, or a third interface that enables the user to provide a set of business rules as recited in amended claim 1.

Therefore, Applicants respectfully submit that the above-identified differences, along with other difference, establish that the subject matter as a whole of amended claim would not have been obvious at the time of invention to a person of ordinary skill in the art. Accordingly, Applicants respectfully submit that amended claim 1 is allowable over the cited references.

Applicants respectfully submit that independent claims 27 and 34 are allowable for at least a similar rationale as discussed above for the allowability of claim 1, and others. Applicants respectfully submit that dependent claims 2-12, 28-33, 35 that depend directly and/or

indirectly from the independent claims 1, 27, and 34 respectively, are also allowable for at least a similar rationale as discussed above for the allowability of the independent claims. Applicants further respectfully submit that the dependent claims recite additional features that make the dependent claims allowable for additional reasons, some of which may be discussed below.

For example, claim 2 recites if the input information is acceptable, storing the input information. The Office Action merely alleges that the above feature is inherent because data is saved in SLIM. However, the Office Action again relies on a possibility to develop an inherency argument, and as such SLIM fails to illustrate that the “descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” (Emphasis added). One of ordinary skill in the art would not recognize that it is necessarily present that the data be saved in SLIM if approved as recited in amended claim 1.

Unless otherwise specified, amendments to the claims are made for the purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof.

While Applicants do not necessarily agree with the prior art rejections set forth in the Office Action, these amendments may be made to expedite issuance of the Application. Applicants reserve the right to pursue claims to subject matter similar to those pending before the present Amendment in co-pending or subsequent applications.

Accordingly, Applicants respectfully traverse the rejections to claims 3 and 29 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based on SLIM in view of Strong. Applicants respectfully traverse the rejections to claims 6, 7, 32, and 33 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based on SLIM in view of Hughes.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

/Sean F. Parmenter/  
Sean F. Parmenter  
Reg. No. 53,437

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
SFP:lls  
61331957 v1